REMARKS

Claims 1-26 and 28-30 were previous pending. Claims 28-30 have been withdrawn from consideration. New claim 31 has been added. Therefore, claims 1-26 and 28-31 will be pending upon entry of current amendments. Claim 1 has been amended. The amendments to claim 1 are at least supported by the disclosures in page 6, line 36 to page 7, line 4. Support for new claim 31 can be found in page 9, line 27 of the specification.

Brief Summary of Claimed Subject Matter

The subject matter of currently amended claim 1 relates to a multifunctional synthetic bioabsorbable device comprising a synthetic bioabsorbable **oriented** polymeric matrix with particles of a pharmacological agent dispersed therein and **cavities** formed around said particles. *See* page 6, line 17 to page 7, line 4; claim 1.

Claim Rejections -- 35 U.S.C. §103

Applicants respectfully traverse the rejections of claims 1-26 as allegedly being rendered obvious by Fischer et al. (EP 1157708; "Fischer") in view of Vogt et al. (US 2008/0058733; "Vogt") under 35 U.S.C. §103(a).

Claim 1 recites a multifunctional synthetic bioabsorbable device comprising: a synthetic bioabsorbable oriented polymeric matrix, particles of a pharmacological agent, cavities induced around the solid particles of the pharmacological agent dispersed in said synthetic bioabsorbable oriented polymeric matrix, wherein the pharmacological agent is capable of retaining its solid particulate form in the melt-processing temperature of the matrix.

The Office Action states that the phrase in the previously presented claim 1, "said cavities existing in said matrix as a result of orientation and mechanical solid-state processing of a mixture of the matrix and said particles," is treated as a product-by-process limitation (Office Action, page 3, lines 8-12). This phrase has been deleted in claim 1. Instead, claim 1 has been amended to recited a synthetic bioabsorbable **oriented** polymeric matrix with cavities around the solid particles of the pharmaceutical agent dispersed therein. "Oriented" is a structural property of the claimed bioabsorbable polymeric matrix and can be detected. Further, orientation of the matrix causes the cavities to be formed around the solid particles of the pharmacological agent dispersed in the matrix. Neither Fischer nor Vogt discloses a multifunctional synthetic

bioabsorbable device comprising a synthetic bioabsorbable **oriented** polymeric matrix.

Furthermore, Fischer and Vogt, even when taken in combination, do not teach or suggest a synthetic bioabsorbable device comprising cavities induced around the solid particles of the pharmacological agent dispersed in said synthetic bioabsorbable oriented polymeric matrix. Fischer fails to disclose particles of a pharmacological agent dispersed in the synthetic bioabsorbable polymeric matrix at all, let alone cavities induced around such particles. Fischer only mentions that the antimicrobial agent within the polymer is homogeneously dispersed through the surgical device, such as biocompatible filaments or yarns (paragraph [0007]). The discussions in Fischer fails to disclose any effect on the physical structure (e.g. forming cavities) of the bioabsorbable device brought about by the presence of the antimicrobial agent in the polymeric matrix.

Vogt teaches a composite comprising two different types of polymers: hydrophilic polymers and hydrophobic polymers (paragraph [0009]). The formation of cavities results from the dissolution of the hydrophilic polymeric part of the composite while the hydrophobic matrix remains as a porous residue (paragraph [0009]). Therefore, the presence of the cavities in the composite of Vogt is due to the dissolution of the hydrophilic polymer component in the matrix; the antibiotics in the composite do not contribute to the formation of the cavities. In addition, the cavities in Vogt do not exist prior to the introduction of the composite in contact with the tissue, because they are formed "*in situ*." Vogt, paragraph [0009] ("This means that the formation of microporous, interconnecting cavities takes place only with the effect of an aqueous and/or physiological environment under *in situ* conditions.") In the present claim 1, the cavities in the matrix and the advantageous mechanical properties resulting therefrom exist already in the product prior to its introduction into the tissue.

Claim 1 recites bioabsorbable polymers, such as poly-α-hydroxy acid polymers or copolymers (page 9, lines 19-27). These bioabsorbable polymers are hydrolyzed by the effect of water to monomers which are used as cell nutrients. Vogt employs polymers that are not bioabsorbable, such as poly(methacrylic acid ester), poly(acrylic acid ester) or their copolymers (paragraph [0011]). The composite of Vogt also comprises hydrophilic polymers that are quickly released into the organism upon introduction of the composite into the tissue.

For at least the foregoing reasons, Fischer and Vogt do not teach or suggest a synthetic bioabsorbable device comprising cavities induced around the solid particles of the pharmacological agent dispersed in said synthetic bioabsorbable oriented polymeric matrix, as recited in claim 1. Claims 1-26 would not have been obvious over Fischer in view of Vogt. Withdrawal of the rejections are respectfully requested.

CONCLUSION

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees that are required in connection with the filing of this response are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon LLP Deposit Account No. 11-0600.

Respectfully submitted,

Dated: January 28, 2009

/Zeba Ali/
Zeba Ali
Reg. No. 51,392

Kenyon & Kenyon LLP
1500 K Street, N.W., Suite 700
Washington, D.C. 20005
Telephone: (202) 220-4200
Facsimile: (202) 220-4201